

JUN - 9 2003

K031663

**Attachment B:**  
*Summary of Safety and Effectiveness*  
*Prepared in accordance with 21 CFR Part 807.92(c).*



GE Medical Systems

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

**Section a):**

1. Submitter: GE Medical Systems  
PO Box 414  
Milwaukee, WI 53201  
  
Contact Person: Allen Schuh,  
Manager, Safety and Regulatory Engineering  
Telephone: 414-647-4385; Fax: 414-647-4090  
  
Date Prepared: May 27, 2003
2. Device Name: GE Vivid 7 Diagnostic Ultrasound System with TSI  
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO  
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
3. Marketed Device: GE Vivid 7 Diagnostic Ultrasound System K003931 (90-IYO/IYN)  
A device currently in commercial distribution.
4. Device Description: The GE Vivid 7 Diagnostic Ultrasound is a full featured echocardiography imaging and analysis system. It consists of a mobile console approximately 65 cm wide, 96 cm deep and 139 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT display. This modification will provide users with enhanced ability to evaluate wall motion during echocardiography.
5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).
6. Comparison with Predicate Device: The GE Vivid 7 with TSI is of a comparable type and substantially equivalent to the current GE Vivid 7. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

**Section b):**

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. Clinical Tests: None required.
3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vivid 7 Diagnostic Ultrasound with TSI is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUN - 9 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Allen Schuh  
Manager, GE Ultrasound Safety  
and Regulatory Engineering  
GE Medical Systems  
P.O. Box 414  
MILWAUKEE WI 53201

Re: K031663  
Trade Name: GE Vivid 7 with TSI  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasound pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: 90 IYN, IYO, and ITX  
Dated: May 27, 2003  
Received: May 29, 2003

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid 7 with TSI, as described in your premarket notification:

Transducer Model Number

3.5C  
5C  
8C

M7C  
7L  
10L  
12L  
M12L  
3S  
5S  
7S  
10S  
M3S  
E8C  
6T  
7T  
8T  
9T  
P2D  
P6D  
i8L  
i13L

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

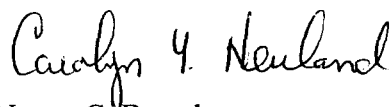
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

  
for Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P			
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular	P	P	P	P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P			
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal	P	P	P		P	P	P	P			
Transvaginal	P	P	P		P	P	P	P			
Transurethral											
Intraoperative <sup>[5]</sup>	P	P	P	P	P	P	P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number   K031663  

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 3.5C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

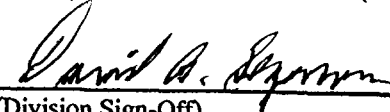
Notes: [1] Abdominal includes GYN;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

Prescription User (Per 21 CFR 801.109)

510(k) Number 5031663

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 5C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P		P	
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P		P	
Pediatric	P	P	P		P	P	P	P		P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P		P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

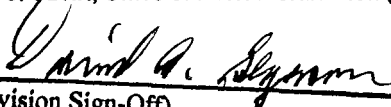
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E		E	
Pediatric	E	E	E		E	E	E	E		E	
Small Organ (specify)	E	E	E		E	E	E	E		E	
Neonatal Cephalic	E	E	E		E	E	E	E		E	
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E		E	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

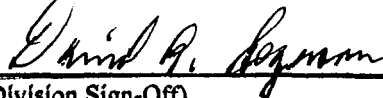
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 5031663



**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with M7C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	E	E	E		E	E	E	E		E	
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E		E	
Pediatric	E	E	E		E	E	E	E		E	
Small Organ (specify)	E	E	E		E	E	E	E		E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E		E	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

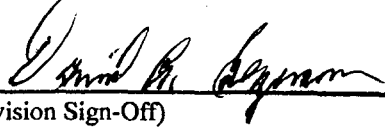
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

  
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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number       K031663      

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 7L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P		P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P		P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P		P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P		P	
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

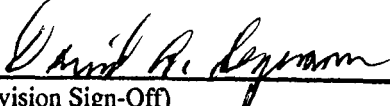
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 10L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P		P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P		P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P		P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P		P	
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[5]</sup>	P	P	P		P		P	P			
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

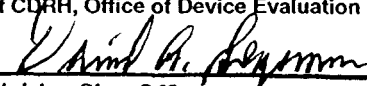
Notes: [2] Small organ includes breast, testes, thyroid.

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P		P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P		P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P		P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P		P	
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

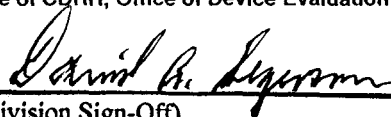
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with M12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	E	E	E		E	E	E	E		E	
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E		E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E		E	
Musculo-skeletal Conventional	E	E	E		E	E	E	E		E	
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)	E	E	E		E	E	E	E		E	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDH, Office of Device Evaluation (ODE)

*David A. Seymour*  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number 5031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 3S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Regan*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 5S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CD RH, Office of Device Evaluation (ODE)

  
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Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K031463

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 7S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;


[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology and GYN.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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510(k) Number K031663

Prescription User (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 10S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
<i>Anatomy/Region of Interest</i>										
Ophthalmic										
Fetal / Obstetrics										
Abdominal										
Pediatric	P	P	P	P	P	P	P	P	P	
Small Organ (specify)										
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	
Adult Cephalic										
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Lyman*  
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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K031663

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with M3S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	P	P	P	P	P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal and GYN;

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRI, Office of Device Evaluation (ODE)

  
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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number 5031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with E8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P			
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P			
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P			
Transvaginal	P	P	P		P	P	P	P			
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

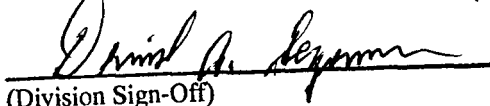
Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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 and Radiological Devices

510(k) Number 5031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 6T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

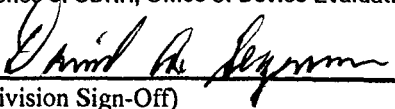
Clinical Application Anatomy/ Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 7T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/ Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E		
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number 2031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 8T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric;

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDPH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number 5031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with 9T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/ Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E		
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

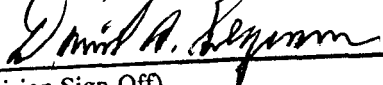
Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

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Concurrence of CDH, Office of Device Evaluation (ODE)



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 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K831663



**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with P6D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
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Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with i8L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics										
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P		
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac <sup>[3]</sup>	P	P	P		P	P	P	P		
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative <sup>[5]</sup>	P	P	P		P	P	P	P		
Intraoperative Neurological										
Intravascular										
Laparoscopic										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal is via Intraoperative;

[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal,  
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510(k) Number 7031663

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vivid 7 with i13L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P		P	P	P	P			
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[5]</sup>	P	P	P		P	P	P	P			
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal is via Intraoperative;

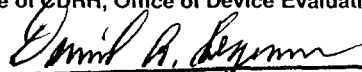
[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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**Concurrence of CDH, Office of Device Evaluation (ODE)**



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510(k) Number     K031663    

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